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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301

EXAMINER

VENKAT, JYOTHSNA A

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/30/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Applicant(s)

10/022,482

Applicant(s)

SHACKNAI ET AL.

Office Action Summary

Examiner

JYOTHSNA A VENKAT

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 and 81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-62 and 81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10,11,12
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of supplemental IDS, supplemental IDS, IDS, extension of time and amendment B filed on 7/24/03, 8/20/03, 7/23/03, 9/15/03 and 9/16/03. Claims 63-80 have been cancelled as per applicant's amendment dated 9/16/03. Claims 1-62 and 81 are pending in the application and the status of the application is as follows;

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-12, 14-42, 44-62- and 81 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a written description rejection.**

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to “ *a method for absorbing irritants in the skin and delivering sulfur to the skin comprising applying a composition, wherein the composition comprises one or high sorption bases, sulfur and one or more sulfur derivatives; absorbing irritants from the skin with the composition; and*

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delivering sulfur to the skin, wherein the skin comprises one or more of the group consisting of epidermis, dermis, and stratum corneum.

The specification at page 2, paragraphs 6-9 define the derivatives of sulfur as selenium sulfides, potassium sulfides. These two compounds belong to the class of inorganic sulfides claimed in claim 11. The specification then describes poly-potassium sulfide, poly-calcium sulfide and then describes the compounds like thiols, organic salts and organic sulfides where R is an organic compound and its salt that can bind ionically or covalently to sulfur. The two compounds described are sodium mercaptoacetic acid. This corresponds to R being acetyl group linked covalently to sulfur and the other valence is attached to sodium atom. The next compound described is glutathione, which is a tripeptide. The instant application fails to describe the nature of R. Organic by definition includes various groups. It can be unsubstituted or substituted alkyl, alkenyl, aryl, acyl, and heterocyclic. Thus the group R can include very different moieties like large peptides to the small organic molecules like monocyclic heterocyclic compounds to the simple thioglycolic acid. The same is true for Sulfites, and metabisulfites. The expression sulfur derivatives, does not meet the written description requirement as one of ordinary skill in the art could not recognize or understand the compounds from mere recitation of R being organic radical in the organic sulfide category and to the nature of inorganic in inorganic sulfites, metabisulfites. Claims employing sulfur derivatives at the point of novelty, such as applicants', neither provide guidance as to the nature R that is required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. Applicants claimed expression represents only an invitation to experiment regarding possible

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compounds suitable as sulfur derivatives, which can be used in the compositions for absorbing irritants in the skin and delivering sulfur.

Response to Arguments

3. Applicant's arguments filed 9/16/03 have been fully considered but they are not persuasive.
4. Applicants argue that the term "sulfur derivatives" is known to one of ordinary skill in the art and submit exhibit, A which lists 82 patents that use the term "sulfur derivatives" and point out that one of ordinary skill in the art would understand "sulfur derivatives".
5. In response to the above argument, it is the position of the examiner that mere listing of patents that use the term "sulfur derivatives" cannot obviate the rejection based upon the written description requirement. The specification fails to define the nature of the "R" at page 2, paragraphs 7 and 8 of the specification. The specification defines "R" at paragraphs 7 and 8 as "where in R is an inorganic element or organic compound that can bind ionically or covalently to sulfur". There is no definition for organic compound. The only compounds exemplified when R is organic are sodium mercaptoacetic acid and glutathione. Simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or subgenuses. The specification does not convey to one of ordinary skill in the art that the inventor possessed the claimed invention at the time of the filing drawn to methods and composition where in the active ingredient is "sulfur derivatives" encompassed by all the compounds drawn to "R" where in R is an inorganic element or organic compound that can bind ionically or covalently to sulfur.

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6. Claims 1-12, 14-42, 44-62 and 81 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant application is claiming *a method for absorbing irritants in the skin and delivering sulfur to the skin comprising*

applying a composition, wherein the composition comprises one or high sorption bases, sulfur and one or more sulfur derivatives;

absorbing irritants from the skin with the composition; and

delivering sulfur to the skin, wherein the skin comprises one or more of the group consisting of epidermis, dermis, and stratum corneum. The three choices of sulfur derivatives claimed in claim 11 and 41 are “sulfur trioxide, sulfuric acid and hydrogen sulfide”. All the three compounds are not useful to practise the claimed invention because hydrogen sulfide is a poisonous gas with a characteristic smell of rotten eggs. Applicants’ attention is drawn to the relevant pages of Merck Index. Merck index also discloses that sulfuric acid is corrosive to all body tissues. The specification fails to disclose the nature of the acid. The same is true for sulfur trioxide. The Merck Index sulfur trioxide as irritant and corrosive to mucous membranes and at the low concentration of 1PPM may cause coughing, choking and severe discomfort. The instant application is claiming a method using sulfur. Applicant’s attention is drawn to “Maibach et al., in the Journal of American Academy of Dermatology pp, 154-155(1990). Applicants in the parent application S.NO provide this article. 09/607,88. The article clearly teaches that using 6% sulfur in the base petrolatum is effective and higher concentration of sulfur is toxic. The instant

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specification fails to describe the concentration of these three components and the subjects that have been treated using these components in the composition. Based upon the above facts, it is the examiner position that only specific concentration of sulfur can be used for the claimed method without causing toxicity, and also the three sulfur derivatives mentioned supra cannot be used for the claimed method. See *In re Marzocchi* 169, USPQ 367.

Response to Arguments

7. Applicant's arguments filed 9/16/03 have been fully considered but they are not persuasive.

8. Applicants argue that the claimed composition comprises more than any of these compounds like hydrogen sulfide, sulfur trioxide and point out that these chemicals may behave differently when used in combination than alone.

9. In response to the above argument, it is the examiners position that the compounds like hydrogen sulfide and sulfur trioxide, sulfuric acids which all under the category of "sulfur derivatives" are toxic and applicants did not submit any evidence that these compounds when used in combination behave differently than alone.

10. Applicants submit exhibit B and point out that the FDA acceptable concentration ranges in topical drug products is 3-10 % and argue that that one of ordinary skill in the art would know that these ranges are acceptable and thus the requirement of 112, 1st paragraph are fulfilled.

In response to the above argument, it is the examiners position that the claims are not limited to the range of sulfur as 5% which is disclosed in the specification. The claims do not recite any specific concentration and according to FDA the acceptable concentration is 3-10% for topical application of sulfur and the specification discloses only 5% as the concentration for sulfur.

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Therefore it is the examiners position that any concentration of sulfur is not suitable for topical application. *In re Marzocchi* 169, USPQ 367.

11. Claims 1-12, 14-42,44-62 and 81 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using the claimed using the compositions which has sulfur and sodium sulfacetamide, does not reasonably provide enablement for claimed method for absorbing irritants in the skin or method of delivering sulfur and absorbing irritants to the skin using sulfur and sulfur derivatives or sulfur and the various sulfur derivatives claimed in the Markush group. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims..

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. See *In re Wands*, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1998). The court set forth the eight factors to consider when assessing if a disclosure would require undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546, the court recited eight factors

These factors include, but are not limited to:

- 1) *The breadth of the claims,*
- 2) *The nature of the invention,*
- 3) *The state of the prior art,*
- 4) *The level of one of ordinary skill,*
- 5) *The level of predictability in the art,*

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6) *The amount of direction provided by the inventor,*

7) *The existence of working examples*

8) *The quantity of experimentation needed to make or use the invention based on the content of the disclosure.*

(1 and 2) The breadth of the claims and the nature of the invention: The claims are drawn to *method for absorbing irritants in the skin and delivering sulfur to the skin comprising applying a composition, wherein the composition comprises one or high sorption bases, sulfur and one or more sulfur derivatives;*

absorbing irritants from the skin with the composition; and

delivering sulfur to the skin, wherein the skin comprises one or more of the group consisting of epidermis, dermis, and stratum corneum. and method of delivering sulfur to the skin and for absorbing irritants in the skin (claim 81)

3. The state of the prior art: *The art cited above by Maibach et al., clearly teaches that sulfur at certain concentration causes toxicity. Applicant's attention is drawn to col.2, page 155, where the article teaches that infant treated with 10% sulfur had illness and at the last paragraph Maibach et al., state that 6% sulfur is not toxic.*

(6-7) The amount of direction provided by the inventors and the existence of working examples: *Applicants have provided at page 12 of specification data with respect to the four formulations A, B, C and D. All the four formulations use sulfur and sodium sulfacetamide as the sulfur derivative for the claimed method. The specification describes various compounds for the sulfur derivatives. See the written description rejection. The specification fails to describe the*

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nature R for the organic sulfide and nature of R for the sulfites and inorganic sulfites. None of the sulfur derivatives are art-recognized equivalents. They are drawn to divergent compounds.

(8) The quantity of experimentation needed to make or use the invention bases on the content of the disclosure: *The claims recite " sulfur derivatives , organic sulfides, cationic sulfur compounds, bisulfides, sulfur trioxide, sulfuric acid, thiols. The instant specification gives no indication to one skilled in the art, that one could use the combination of sulfur with different sulfur derivatives, which are divergent in nature and have a reasonable expectation of success. Due to the divergent nature of the sulfur derivatives, one of ordinary skill in the art cannot extrapolate the test results to all the sulfur derivatives, and the practice of the full scope of the invention would require undue experimentation.*

Response to Arguments

12. Applicant's arguments filed 9/16/03 have been fully considered but they are not persuasive.

Applicants point out that in order to practice the *Wands* invention, extensive (but not undue) experimentation was required, but this did not preclude a finding that Wands claims were enabled and therefore since applicants claims do not require undue experimentation, applicants claims are still enabled and the specification teaches what the invention is and how to use it, so that one skilled in the art can practise the invention as claimed without the burden of undue experimentation and thus the claims comply with 112, 1st paragraph.

In response to the above argument, it is the position of the examiner that applicants have provided at page 12 of specification data with respect to the four formulations A, B, C and D. All the four formulations use sulfur and sodium sulfacetamide as the sulfur derivative for the

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claimed method. The specification describes various compounds for the sulfur derivatives. See the written description rejection. The specification fails to describe the nature R for the organic sulfide and nature of R for the sulfites and inorganic sulfites. None of the sulfur derivatives are art-recognized equivalents. They are drawn to divergent compounds.

The claims recite “ sulfur derivatives, organic sulfides, cationic sulfur compounds, bisulfides, sulfur trioxide, sulfuric acid, thiols. The instant specification gives no indication to one skilled in the art, that one could use the combination of sulfur with different sulfur derivatives, which are divergent in nature and have a reasonable expectation of success. Due to the divergent nature of the sulfur derivatives, **one of ordinary skill in the art cannot extrapolate the test results to all the sulfur derivatives, and the practice of the full scope of the invention would require undue experimentation.**

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1, 11-15, 30-31, 33-36, 41-45, 56, 60 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by sulfur revisited article” by Lin et al in American Journal of Dermatology pp553-558 (1988).

15. **Applicants are notified that the Lin article is not provided with this office action as it is cited by applicants and provided to the examiner in the parent application.**

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Claim 30 is drawn to the irritants, sweat and sebum and the article anticipates the claimed method, as the sulfur is useful for treating acne, see table II. The claimed method is inherent. Bentonite reads on the claimed clay. See table IV.

Response to Arguments

16. Applicant's arguments filed 9/16/03 have been fully considered but they are not persuasive.

Applicants argue that the compositions in Table IV with bentonite do not also include sulfur and sulfur derivatives and therefore do not anticipate the claims and nothing in table III anticipates the claimed method which is absorbing irritants in the skin and delivering sulfur to the skin.

In response to the above argument, it is the position of the examiner that Table IV discloses topical preparations that contain sulfur and sulfacetamide. Applicant's attention is drawn to SulfacetR-R acne lotion which reads on the claims that recite sulfur and sulfur derivatives. The lotion reads on the sorption bas. The claims recite "*method for absorbing irritants in the skin and delivering sulfur to the skin comprising applying a composition, wherein the composition comprises one or high sorption bases, sulfur and one or more sulfur derivatives; absorbing irritants from the skin with the composition; and*

delivering sulfur to the skin, wherein the skin comprises one or more of the group consisting of epidermis ,dermis, and stratum corneum. and method of delivering sulfur to the skin and for absorbing irritants in the skin (claim 81). One of the Markush choices for absorbing irritants is sebum. The claimed method is inherent as the article discloses the sulfur

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being useful for treating acne and Rosacea. Acne is caused by sebum and sometimes acne is caused by contact with chemicals. Rosacea is caused by certain irritant foods. This method reads on the broad claim which does not specify the irritants. Therefore the claimed method is inherent.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1-60 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Lin et al article cited in 102 rejection and U. S. Patent 4,388,301 ('301) and Skin care and cosmetic ingredients dictionary, page 317(1994).

The instant application is claiming *a method for absorbing irritants in the skin and delivering sulfur to the skin comprising*

applying a composition, wherein the composition comprises one or high sorption bases, sulfur and one or more sulfur derivatives;

absorbing irritants from the skin with the composition; and

delivering sulfur to the skin, wherein the skin comprises one or more of the group consisting of epidermis ,dermis, and stratum corneum

and the composition comprises sorption base which can be silica or clay or gum or swelling clay.

The Lin et al., article as explained in the 102 section discloses the claimed method of absorbing the irritant which is sweat and sebum by using sulfur and sulfacetamide. Some of the formulation disclosed in table IV of the article uses bentonite which belongs to clay. The difference between the article and the instant application is the article does not teach the limitations claimed in the dependent claims with respect to silica and gum and specific clays. However the patent '301 teaches treating acne-using polysulfide compounds which is claimed in the instant application as the sulfur derivative along with clays and silica. See the abstract, see cols.2-3, see col.3, lines 50 et seq for the different clays and see examples. The example IV teaches silica and silicates. The patent does not teach gum. Gums are used as gelling agents or thickeners in the formulations. The skin care dictionary teaches Xanthum gum as a thickener.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare compositions of the Lin et al., article and combine it with the *clays and silica* of '301, and combine it with xanthan gum taught by the dictionary as a thickener in the formulations, expecting beneficial effect to the skin, which is absorbing irritants like sweat and sebum that causes acne. The motivation to combine the ingredients silica

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and clays flows logically from the art for having been used in the same compositions for treating acne and the motivation to use any gum or xanthan gum stems from the scientific fact that the gums are used in the formulations as thickeners or gelling agents. This is a prima facie case of obvious ness.

Response to Arguments

20. Applicant's arguments filed 9/16/03 have been fully considered but they are not persuasive.

The gist of applicants arguments is that the Lin article does not teach the claimed method of absorbing irritants and the patent '301 teaches sulfur derivatives for treating acne and the instant claims are not drawn to treating acne but for the delivery of sulfur to the skin, and applicants argue that neither the article nor the patent '301 mention thickeners or gelling agents being advantageous to their invention.

In response to the above argument, it is the position of the examiner that the both the article and the patent teaches treating acne using sulfur and sulfur derivatives like sodium sulfacetamide and Zinc sulfate. Acne is caused by irritant like sebum and when acne is treated topically, it means that the active ingredient is absorbed which implies, the deliver of sulfur to the skin. The patent '301 teaches sulfur derivatives which is polysulfide compounds for treating acne along with clays and silica. Therefore one of ordinary skill in the art would reasonably expect that by using the lotions of the article which has sulfur and combining it with sulfur derivatives like polysulfides along with clays and silica would expect reasonable amount of success in delivering sulfur to the skin as both the references uses these compounds for the

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treatment of acne and since acne is caused by irritant sebum one of ordinary skill in the art would be motivated to prepare compositions of Lin article and combine it with sulfur derivatives and clays and silica expecting delivery of sulfur to the skin. Gums are used for the known property as thickeners or gelling agents and one of ordinary skill in the art would be motivated to use gums expecting that the formulation would be viscous.

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

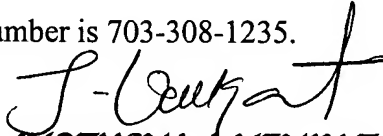
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTHSNA A VENKAT whose telephone number is 703-308-2439. The examiner can normally be reached on Monday-Thursday, 9:30-7:30:1st and 2nd Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN K PAGE can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


JYOTHSNA A VENKAT
Primary Examiner
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